



ACN 007 988 767

Phone: +61 8 8234 2660 Fax: +61 8 8234 6268 Address: 38 Winwood Street Thebarton South Australia 5031 www.bresagen.com

# **FACSIMILE TRANSMISSION**

TO:

The Office of International Corporate Finance

COMPANY:

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**FAX NUMBER:** 

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FROM:

Trudy Fenton

DATE:

Thursday, 8 August 2002

SUBJECT:

**ASX** Announcements

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In accordance with our obligation as a 12g3-2(b) filer, number 82-5135, to file home country announcements, please find the following announcement which was released through the Australian Stock Exchange today —

1. Media Release: BresaGen announces FDA approval for proprietary cell delivery dated 8 August, 2002.

Yours sincerely

Trudy Fenton

Corporate Administrator tfenton@bresagen.com.au

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### Thursday, 8 August 2002



# BresaGen Announces FDA Approval for Proprietary Cell Delivery Device

ADELAIDE, S.A. and ATHENS, GA., U.S.A., August 8, 2002 - Biotechnology company, BresaGen Limited today announced that it has received approval from the U.S. Food and Drug Administration (FDA) to market its proprietary catheter which is intended to be used for delivery of therapeutic agents into the brain.

Under the FDA 510(k) clearance, BresaGen's catheter can now be marketed for intracranial delivery of stern cells and drugs in patients with stroke and neurodegenerative diseases and disorders.

BresaGen's Chief Scientific Officer, Dr Allan Robins, explained: "The cell delivery catheter that BresaGen has developed aims to reduce damage to brain tissue. The catheter tip is visible under magnetic resonance imaging (MRI), allowing cells to be delivered to target locations with greater accuracy than possible with currently used catheters."

Studies have demonstrated that Parkinson's disease symptoms can be improved by transplanting dopamine secreting cells into the striatum of the brain, with accurate cell delivery a critical part of the procedure. A proprietary catheter and method for delivering living cells into patients with neurological diseases, such as Parkinson's, is a major step toward the commercialisation of this treatment, according to Dr. Robins. The specific features of the cell delivery device are disclosed in a US patent application that is licensed exclusively to BresaGen by the University of Minnesota. Extensive research was performed on the catheter by scientists and engineers at the University of Minnesota, Virginia Commonwealth University, and the University of Toronto.

Dr Robins said that BresaGen's catheter has a unique design and specialized biomaterials which minimize shear force stress on cell membranes as the cells are injected through the catheter.

BresaGen President and CEO, Dr John Smeaton, added: "BresaGen is developing a comprehensive cell therapy product line that includes cells derived from stem cells, catheter devices to accurately deliver the cells into target locations, and imaging technologies to evaluate pre and post-operatively the condition of the local tissue environment. The approval from the FDA to market the catheter significantly extends BresaGen's cell delivery program," Dr Smeaton said.

BresaGen's announcement is the latest in a series of recent developments regarding stem cells, which are defined by their ability to grow into many different adult cell types. Several recent studies indicate that stem cell therapy may be effective in the treatment of traumatic spinal cord injury and stroke, as well as for neuro-degenerative disorders such as Huntington's disease, Alzheimer's and Parkinson's. President George Bush announced last August that the US federal government would fund research on existing stem cell lines. Four of the stem cell lines sanctioned for NIH funded research are owned by BresaGen. More information on BresaGen's products is available at www.bresagen.com.

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#### For further information contact:

BresaGen Ltd
Dr John Smeaton
CEO and President
Phone: 08 8234 2660
Mob: 0408 823426

Email: jsmeaton@bresagen.com.au

Media contact for BresaGen Ltd

Hilarie Dunn and Associates Phone: 02 9251 0110 Mobile: 0414 357792

Email: hilariedunn@bigpond.com.au

#### **About BresaGen Limited**

BresaGen is a biotechnology company committed to the discovery and commercial development of innovative bio-therapies. Drawing on two decades of experience, the company has earned a reputation for excellence in the fields of reproductive and developmental biology and in the manufacture of recombinant protein pharmaceuticals. The Company has offices and laboratories in Adelaide, Australia and Athens, Georgia USA.

The Cell Therapy division has a product development program that takes the company's proprietary position in embryonic stem cell differentiation and applies it to the treatment of central nervous system diseases including Parkinson's Disease. The division includes an extensive program developing catheter and imaging technology for neurosurgical cell delivery.

The Protein Pharmaceuticals division operates a GMP facility with experience in process development for the manufacture of recombinant proteins.

This press release contains forward-looking statements that reflect the Company's current expectations regarding future events. Forward-looking statements involve risks and uncertainties. Actual events could differ materially from those projected herein and depend on a number of factors including the success of the Company's research strategies, the applicability of the discoveries made therein, the successful and timely completion of clinical studies and the uncertainties related to the regulatory process.